

RESULTS

Test results will be displayed on the screen when the test is complete. Calculated results are displayed after the **DATA** button is pressed.

	mg/dL to mmol/L <i>divide mg/dL by</i>	mmol/L to mg/dL <i>multiply mmol/L by</i>
TC	38.664	38.664
HDL	38.664	38.664
TRG	88.54	88.54
LDL	38.664	38.664
GLU	18.018	18.018

QUALITY CONTROL

External quality control material should be run routinely to show that your system is giving accurate results. We recommend the following quality control procedures for the Cholestech LDX System.

Choice of Materials

Liquid Level 1 and Level 2 controls that work well with the Cholestech LDX System are available. If you use other controls, you will need to establish ranges for the Cholestech LDX System.

Handling

- Follow the instructions that come with your controls.
- Check the expiration date before use. Do not use if expired.
- See “Running a Test” for the procedure.

External Quality Control

External control material should be used to demonstrate that the reagents and the assay procedure perform properly. Good Laboratory Practice principles suggest that controls should be run whenever the laboratory director has any question about test system integrity, reagent storage conditions, or the reliability of any test result.

If the controls do not perform as expected, repeat the test or contact Abbott Product Support before testing patient samples.

Controls should be tested:

- With each new lot of cassettes;
- With every new shipment of cassettes, even if the lot has been received previously;
- When reagents may have been stored or handled in a way that can degrade their performance;
- As otherwise required by your laboratory’s standard quality control procedures;
- As otherwise required by federal, state and local guidelines.

Record the results in a Quality Control Log.

The quality control results should be in range before testing patient samples. See the Cholestech LDX System User Manual if they are not. Please call Abbott Product Support to report any problems or if you have any questions about quality control.

LIMITATIONS

Analyte	Measuring Range	For results outside the measuring range, the LDX displays:	
		Low	High
TC	100 – 500 (2.59 –12.9)	<100 mg/dL (<2.59 mmol/L)	>500 mg/dL (>12.9 mmol/L)
HDL	15–100 (0.39–2.59)	<15 mg/dL (<0.39 mmol/L)	>100 mg/dL (>2.59 mmol/L)
TRG	45 – 650 (0.51–7.34)	<45 mg/dL (<0.51 mmol/L)	>650 mg/dL (>7.34 mmol/L)
GLU	50 – 500 (2.78 – 27.8)	<50 mg/dL (<2.78 mmol/L)	>500 mg/dL (>27.8 mmol/L)

Additional Limitations That Display N/A:

- If the measured value of TRG is >650 mg/dL (>7.34 mmol/L), the Cholestech LDX Analyzer displays “N/A” for HDL.
- If the measured value of TRG is >400 mg/dL (>4.51 mmol/L), the Cholestech LDX Analyzer displays “N/A” for the LDL estimate.
- If the measured value of TC, HDL or TRG is outside the measuring range, the Cholestech LDX Analyzer displays “N/A” for the LDL estimate.

Additional Limitations:

- The glucose test is specific for D-glucose. Other sugars that may be present in the blood do not react in the glucose test (i.e., fructose, lactose).
- Samples with total cholesterol, HDL cholesterol, triglyceride or glucose values outside the measuring range should be sent to a laboratory for testing.
- Performance of the Cholestech LDX System has not been tested on samples from newborns.
- Blood glucose results performed at altitudes above 5000 feet have not been validated.

Some substances may cause inaccurate results with enzymatic tests. The substances listed below were tested for interference with all analytes. Less than 10% interference was seen at the levels shown.

Ascorbic Acid	1	Hemoglobin	125
Bilirubin	5	Lactose	100
Creatinine	30	Lovastatin (Mevacor)	4
Cysteine	10	Nicotinic Acid (Niacin)	10
Fructose	30	Urea	500
Gemfibrozil (Lopid)	15	Uric Acid	15
Glutathione	1		

- Hematocrits between 30% and 49% do not affect results.
- Blood collection tubes with glycerol should not be used for the triglyceride test.
- Hand creams and soaps with glycerol may cause falsely high triglyceride results.
- The triglyceride test measures triglycerides and free glycerol. Free glycerol usually is less than 20 mg/dL.^{10,11}
- There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.¹²

EXPECTED VALUES

Lipid values are interpreted according to clinical practice guidelines or recommendations that are subject to change over time. Interpretive information for all lipid values is not contained in a single guideline. The following information was compiled from recent guidelines or recommendations of the American College of Cardiology, American Heart Association, and National Lipid Association.^{3,13,14}

Analyte	mg/dL	mmol/L	Classification
TC ^{3,13}	170	4.40	Optimal
HDL	50	1.29	Optimal ^{3,13}
	<40 (men)	<1.03	Low ¹⁴
	<50 (women)	<1.29	Low ¹⁴
TRG ¹⁴	<150	<1.69	Normal
	150 – 199	1.69 – 2.25	Borderline high
	200 – 499	2.26 – 5.64	High
	≥500	≥5.65	Very high
LDL ¹⁴	<100	<2.59	Desirable
	100 – 129	2.59 – 3.34	Above desirable
	130 – 159	3.36 – 4.11	Borderline high
	160 – 189	4.14 – 4.89	High
	≥190	≥4.91	Very high
Non-HDL ¹⁴	<130	<3.36	Desirable
	130 – 159	3.36 – 4.11	Above desirable
	160 – 189	4.14 – 4.89	Borderline high
	190 – 219	4.91 – 5.66	High
	≥220	≥5.69	Very high

TC/HDL Ratio

Clinical practice guidelines do not comment on use of the ratio of total to HDL cholesterol. Various authors have suggested that the TC/HDL ratio is the strongest lipid risk factor and can be a useful summary of coronary heart disease risk.^{15,16} A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of coronary heart disease.¹⁵

Glucose

The American Diabetes Association has identified categories of increased risk for diabetes based upon glucose.¹⁷

- Fasting plasma glucose (FPG) 100-125 mg/dL (5.6-6.9 mmol/L); impaired fasting glucose
- 2-hr plasma glucose in the 75-g oral glucose tolerance test (OGTT) 140–199 mg/dL (7.8–11.0 mmol/L); impaired glucose tolerance

For these tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

The American Diabetes Association has criteria for the diagnosis of diabetes mellitus based upon glucose:¹⁷

- FPG ≥126 mg/dL (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hr.
- 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

In the absence of unequivocal hyperglycemia, diagnosis should be confirmed by repeat testing. When screening for diabetes, any abnormal glucose result should be referred to a physician for further follow-up.

PERFORMANCE CHARACTERISTICS

Representative Data: results in individual laboratories may vary from these data. Individual laboratories results may vary from this study due to differences in the testing protocol, and between instruments, calibrations, reagents, and replicates.

Precision	Within-Run Precision Whole Blood (heparin)		Day-to-Day Precision Commercial Control Material	
	Level 1	Level 2	Level 1	Level 2
Total Cholesterol , n =	10	10	20	20
X (mg/dL) =	299	184	161	244
SD (mg/dL) =	7.3	4.6	4.3	8.6
CV (%) =	2.4	2.5	2.6	3.5
HDL Cholesterol , n =	10	10	20	20
X (mg/dL) =	29	46	29	46
SD (mg/dL) =	1.0	2.2	1.3	2.9
CV (%) =	3.3	4.9	4.4	6.4
Triglycerides , n =	10	10	20	20
X (mg/dL) =	362	256	121	276
SD (mg/dL) =	13.1	4.0	2.8	8.7
CV (%) =	3.6	1.6	2.3	3.2
LDL Cholesterol , n =	10	10	20	20
X (mg/dL) =	197	87	108	143
SD (mg/dL) =	7.5	4.3	4.6	8.4
CV (%) =	3.8	4.9	4.3	5.9
Glucose , n =	10	10	20	20
X (mg/dL) =	103	127	103	311
SD (mg/dL) =	6.4	5.7	3.6	15.4
CV (%) =	6.2	4.5	3.5	4.9

ACCURACY (METHOD COMPARISON)

The cassette total cholesterol was compared with a validated method traceable to the CDC-modified Abell-Kendall reference method traceable to National Institute of Standards and Technology (NIST) standards.

The cassette HDL cholesterol was compared with a validated method, utilizing dextran sulfate/magnesium chloride precipitation and enzymatic cholesterol determination. The HDL cholesterol comparison method is based on the selected method for HDL cholesterol³ and has documented agreement with the CDC Reference Method.

The cassette triglyceride test was compared with a validated method, utilizing hydrolysis with lipase. The comparison method has documented agreement with a CDC Reference Method.

The cassette estimated LDL was compared to that calculated from the above validated total cholesterol, HDL cholesterol and triglycerides methods.

The range of values tested (mg/dL) were as follows:

TC	120 – 300
HDL	26 – 85
TRG	40 – 500
GLU	25 – 575

Results

X = Reference Method (serum)

Y = Cholestech LDX Analyzer (venous whole blood)

Analyte	No. of Pairs	Slope	y-intercept	Correlation Coefficient	Bias at
Total cholesterol	40	0.98	2.41	0.97	200 -1%
HDL cholesterol	40	0.97	0.23	0.95	35 -2%
Triglycerides	40	1.0	0.13	0.99	250 0%
Glucose	40	0.99	1.01	0.98	150 0%

LIMITED WARRANTY

For the applicable warranty period, Abbott warrants that each product shall be (I) of good quality and free of material defects, (II) function in accordance with the material specifications referenced in the product manual, and (III) approved by the proper governmental agencies required for the sale of products for their intended use (the “Limited Warranty”). If the product fails to meet the requirement of the limited warranty, then as a customer’s sole remedy, Abbott shall either repair or replace, at Abbott’s discretion, the product. Except for the limited warranty stated in this section, Abbott disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. Abbott’s maximum liability with any customer claim shall not exceed the net product price paid by customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The Limited Warranty above shall not apply if the customer has subjected the product to physical abuse, misuse, abnormal use, use inconsistent with the product Manual or Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

RETURN POLICY

Please contact Abbott Product Support prior to returning any defective components. Refer to Contact Abbott section for additional information.

CONTACT ABBOTT

Abbott Product Support

Contact one of the following Abbott Product Support Care Centers or your local distributor if you have any questions regarding the use of your Abbott product. You may also contact us at www.globalpointofcare.abbott.

Region	Phone	E Mail Address
Europe & Middle East	+ (44) 161 483 9032	EMEproductsupport@abbott.com
Asia Pacific	+ (61) 7 3363 7711	APproductsupport@abbott.com
Africa, Russia, & CIS	+ (44) 161 483 9032	ARCISproductsupport@abbott.com
Latin America	+ (57) 4824033 (ext. 2)	LAproductsupport@abbott.com
Canada	+ (1) 613 271 1144	CANproductsupport@abbott.com
US	+ (1) 877 441-7440, opt# 2	USproductsupport@abbott.com

Abbott Customer Service

Contact the following Abbott Service Care Center or your local distributor for order and billing assistance. You may also contact us at www.globalpointofcare.abbott.

Phone	E Mail Address
+ (1) 877 441 7440	clientservices@abbott.com

EN For a copy of this product’s instructions for use in English please visit our website.

CS Kopii návodu k použití tohoto výrobku v češtině najdete na našich webových stránkách.

DA Du kan finde en kopi af denne brugerhåndbog på dansk på vores websted.

DE Eine Kopie der Gebrauchsanweisung für dieses Produkt in deutscher Sprache finden Sie auf unserer Website.

EL Για ένα αντίγραφο των οδηγιών χρήσης αυτού του προϊόντος στα Ελληνικά, παρακαλούμε επισκεφθείτε τον ιστότοπό μας.

ES Para obtener una copia de las instrucciones de uso de este producto en español, visite nuestro sitio web.

ET Toote eestikeelse kasutusjuhendi saamiseks külastage meie veebisaiti.

FR Pour obtenir un exemplaire du mode d'emploi de ce produit en français, veuillez consulter notre site Internet.

HU A termékutasítások magyar nyelvű megtekintéséhez keresse fel weboldalunkat.

ID Untuk salinan petunjuk penggunaan produk ini dalam bahasa Inggris, kunjungi situs web kami.

IT Per una copia delle istruzioni di questo prodotto per l'uso in italiano, si prega di visitare il nostro sito web.

KO 본 제품의 한국어 사용 지침을 보시려면 웹사이트를 방문하십시오.

NL Voor een kopie van de gebruiksinstructies van dit product in het Nederlands verwijzen wij u naar onze website.

NO For et eksemplar av dette produktets brukerveiledning på norsk kan du gå til vår nettside.

PL Kopia instrukcji użycia tego produktu w języku polskim jest zamieszczona na naszej witrynie internetowej.

PT Para obter uma cópia das instruções de utilização deste produto em português, viste o nosso site da Web.

PT-BR Para uma cópia das instruções de uso deste produto em português, visite nosso website.

RO Pentru o copie a Instrucțiunilor de utilizare pentru acest produs in limba română vizitați website-ul nostru.

SK Kópiu návodu na používanie tohto produktu v slovenčine nájdete na našej webovej stránke.

SV Besök vår webbplats för att få en kopia av bruksanvisningen på svenska för denna produkt.













TH หากต้องการสำเนาคู่มือผลิตภัณฑ์นี้เป็นภาษาไทย โปรดไปเว็บไซต์ของเรา




TR Bu ürüne ilişkin kullanım talimatlarının Türkçe dilindeki bir kopyası için web sitemizi ziyaret edin.

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GLOSSARY of SYMBOLS

		
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